

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

)
)
) MDL NO. 1456
) Civil Action No. 01-12257-PBS
)

THIS DOCUMENT RELATES TO:

) Judge Patti B. Saris
)

The City of New York v. Abbott Labs., et al.

(S.D.N.Y. No. 04-CV-06054)

County of Suffolk v. Abbott Labs., et al.

(E.D.N.Y. No. CV-03-229)

County of Westchester v. Abbott Labs., et al.

(S.D.N.Y. No. 03-CV-6178)

County of Rockland v. Abbott Labs., et al.

(S.D.N.Y. No. 03-CV-7055)

County of Dutchess v. Abbott Labs, et al.

(S.D.N.Y. No. 05-CV-06458)

County of Putnam v. Abbott Labs, et al.

(S.D.N.Y. No. 05-CV-04740)

County of Washington v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00408)

County of Rensselaer v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00422)

County of Albany v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00425)

County of Warren v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00468)

County of Greene v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00474)

County of Saratoga v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00478)

County of Columbia v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00867)

Essex County v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00878)

County of Chenango v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00354)

County of Broome v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00456)

County of Onondaga v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00088)

County of Tompkins v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00397)

County of Cayuga v. Abbott Labs, et al.

(N.D.N.Y. No. 05-CV-00423))
County of Madison v. Abbott Labs, et al.)
 (N.D.N.Y. No. 05-CV-00714))
County of Cortland v. Abbott Labs, et al.)
 (N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. Abbott Labs, et al.)
 (N.D.N.Y. No. 05-CV-00415))
County of Oneida v. Abbott Labs, et al.)
 (N.D.N.Y. No. 05-CV-00489))
County of Fulton v. Abbott Labs, et al.)
 (N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. Abbott Labs, et al.)
 (N.D.N.Y. No. 05-CV-00479))
County of Jefferson v. Abbott Labs, et al.)
 (N.D.N.Y. No. 05-CV-00715))
County of Lewis v. Abbott Labs, et al.)
 (N.D.N.Y. No. 05-CV-00839))
County of Chautauqua v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06204))
County of Allegany v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06231))
County of Cattaraugus v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06242))
County of Genesee v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06206))
County of Wayne v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06138))
County of Monroe v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06148))
County of Yates v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06172))
County of Niagara v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06296))
County of Seneca v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06370))
County of Orleans v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06371))
County of Ontario v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06373))
County of Schuyler v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06387))
County of Steuben v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06223))
County of Chemung v. Abbott Labs, et al.)
 (W.D.N.Y. No. 05-CV-06744))

AND)
County of Nassau v. Abbott Labs, et al.)
(E.D.N.Y. No. 04-CV-5126))
_____)

**DEFENDANT MEDIMMUNE, INC.’S MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO DISMISS (1) THE CONSOLIDATED COMPLAINT OF NEW YORK
CITY AND PLAINTIFF NEW YORK COUNTIES OTHER THAN NASSAU AND (2)
THE SECOND AMENDED COMPLAINT OF NASSAU COUNTY¹**

¹ MedImmune joins in and hereby incorporates by reference Defendants’ Joint Memorandum of Law in Support of The Motion to Dismiss these same complaints as well as the arguments advanced in the individual memoranda submitted by other Defendants in support of their motions to dismiss these same complaints.

In its three Suffolk County decisions,² the Court dismissed all claims of Suffolk County against MedImmune (and the other “Suffolk 13” Defendants) because Suffolk failed to provide sufficient specific information about MedImmune to satisfy Rule 9(b). The complaints now before the Court seek to revive those claims, but fail to correct those deficiencies. Accordingly, Defendant MedImmune, Inc. (“MedImmune”) has moved to dismiss all counts against it in both the Consolidated Complaint of New York City and Plaintiff New York Counties Other Than Nassau (the “Consolidated Complaint”) and the Second Amended Complaint of Nassau County (the “Nassau SAC”) (collectively, the “Complaints”).

Having now demonstrated, after many tries, an inability or unwillingness to provide the requisite specifics, Plaintiffs’ Complaints merit dismissal.

I. The Complaints Fail To Satisfy Rule 9(b)

Plaintiffs have failed to satisfy Rule 9(b) by failing to particularize the “who, what, when, where and how” of the alleged fraud. Indeed, these Complaints are doomed by their failure to allege with specificity any misstatements or wrongdoing by MedImmune.

Plaintiffs allege that MedImmune has reported a “false and inflated WAC” for its products in order to trigger the publication of a “false and inflated AWP” on “which reimbursements are made.”³ (Cons. Compl. ¶¶ 8, 590-91, Nassau SAC ¶¶ 6, 482-83). They also

² *County of Suffolk v. Abbott Labs.*, 339 F. Supp. 2d 165 (D. Mass. Sep. 30, 2004) (“Suffolk I”); *County of Suffolk v. Abbott Labs.*, Civ. A. 01-12257, 2004 WL 2387125 (D. Mass. Oct. 26, 2004) (“Suffolk II”); Memorandum and Order, *County of Suffolk v. Abbott Labs.*, MDL No. 1456 (D. Mass. Apr. 8, 2005) (“Suffolk III”).

³ In light of this Court’s recognition that, “[t]ypically, the AWP for a brand-name, self-administered drug is 20% or 25% above WAC,” *In re Pharm. Industry Average Wholesale Price Litig.*, 230 F.R.D. 61, 68 (D. Mass. 2005), Plaintiffs allege that the spread between WAC and AWP exceeds the 20-25% range for many drugs. (Cons. Compl. ¶ 8, Nassau SAC ¶ 6). MedImmune, however, is not mentioned in Exhibit F to the Consolidated Complaint, which purports to be examples of drugs for which the spreads between “Published AWP’s & WACs” exceed the 20-25% range.

claim that “market prices” they do not specify, taken from unspecified sources, are “substantially” or “significantly” less than the “false and inflated” AWP and WACs for certain MedImmune products. (Cons. Compl. ¶¶ 590-91, Nassau SAC ¶¶ 482-83). The Complaints do not explain why differences between those “market prices” they cite and the MedImmune AWP and WACs would constitute fraud, and do not provide any basis for the conclusion that MedImmune’s WACs and AWP are false and inflated.

Specifically, Plaintiffs do not allege *any* representation by MedImmune (or any other Defendant) regarding what AWP or WAC means—and certainly no representation by MedImmune that it was ever using either term to refer to an actual price or an actual average of prices.

Plaintiffs allege that AWP is defined either by “industry publications and by the Office of Inspector General (“OIG”) as the average cost paid by retailers to pharmaceutical wholesale suppliers,” (Cons. Compl. ¶ 5), or “[b]y [unspecified] federal and state statute and regulation, and industry practice” as “based upon and directly related to actual prices paid by providers to pharmaceutical manufacture[r]s (or wholesalers) for such prescription drugs.”⁴ (Nassau SAC ¶ 2).

Plaintiffs do not allege what WAC means. (Cons. Compl. ¶ 6, Nassau SAC ¶ 2). But Plaintiffs’ theory that MedImmune reported a false and inflated WAC or AWP requires an allegation that *MedImmune* made a representation that WAC or AWP means what Plaintiffs allege it means. A number is not inherently false—there must be a representation regarding what that number represents. Unless Plaintiffs can specify that MedImmune represented that its AWP or WAC represented actual prices or actual averages of prices paid by retailers, their allegations

⁴ “Based upon” and “related to” are, of course, not the same thing as “defined as.”

that MedImmune published a “false” AWP or WAC fail to state a claim that can survive the Rule 9(b) test.

This lack of specificity is particular troubling because all of MedImmune’s drugs referenced in either Complaint—Respigam, Cytogam and Synagis⁵—are administered by physicians. Under N.Y. Soc. Serv. Law § 367-a(9)(a) & (9)(b)(ii), when the administering physician bills directly and seeks Medicaid reimbursement, such reimbursement is based on “actual cost,” not AWP. N.Y. Soc. Serv. Law § 367-a(9)(a). Thus, Plaintiffs must be aware that AWP is *not* an “actual cost.” And that underscores the need for specific allegations to show how, why and when MedImmune allegedly committed fraud relating to Medicaid reimbursement.

In short, the Complaints lack any allegations that MedImmune made a false representation or acted wrongfully.⁶

II. The Complaints Fail To Satisfy the Bare Minimum of This Court’s Requirements

This Court has been clear that a demonstration of the fraudulent nature of the price for *each specific drug* is a threshold requirement for any claim. The Complaints do not satisfy even that minimum requirement.

⁵ The Consolidated Complaint refers to three MedImmune drugs: Respigam, Cytogam and Synagis, while the Nassau SAC refers only to the latter two.

⁶ In fact, Plaintiffs allege virtually nothing regarding MedImmune. Instead of alleging facts that, taken as true, would state a claim, Plaintiffs rely on, for example, the wholly meaningless allegation that MedImmune has been sued elsewhere. (Consl. Compl. Ex. D). If the extent to which a Defendant is included in other suits were a measure of blameworthiness (which MedImmune denies), MedImmune could respond by pointing out that most other States, including Florida, Illinois, Kentucky, Massachusetts, Wisconsin, Arizona, Montana, and Nevada, when filing similarly-styled lawsuits, have chosen *not* to sue MedImmune.

Plaintiffs have not made any specific Best Prices allegations against MedImmune. But this Court has stated that Plaintiffs must allege specific facts, relating to *each* Defendant, and that merely alleging that the manufacturer “may have reported a fraudulent AWP, without more” will not suffice. *Suffolk II*, 2004 WL 2387125, at *2. Furthermore, to satisfy the requirements of Rule 8(a) this Court has required Suffolk to “set forth at least minimal facts with respect to (1) the allegedly fraudulent or false price reported to the state for *any specific drug*; or (2) any information showing a company-wide scheme to misstate Best Prices.” *Id.* at *3. (emphasis added).

With respect to Suffolk’s fraudulent AWP claims, this Court has required that, to comply with Rule 9(b), the Plaintiffs must plead information sufficient to show that the published AWP for *each* drug was fraudulent by providing the allegedly “fraudulent” AWP for each drug and the “basis for calculating a spread between the published AWP and the actual average price at which the drug is sold by wholesalers.” *Suffolk III* at 1-2. *See also* *Suffolk II*, 2004 WL 2387125, at *2. Plaintiffs have failed to meet even this most basic requirement. Nassau County does not even allege that it actually purchased any of the MedImmune drugs for which it alleges a difference between the so-called “market price” and AWP, or that the products for which it expended the money had an allegedly fraudulent AWP.⁷ And although the Consolidated Complaint purports to seek relief for three MedImmune products, Cytogam, Respigam, and Synagis, (Cons. Compl. Ex. A at 50), Plaintiffs provide an allegedly “fraudulent AWP” and “market price” for *only one* of the three products: Cytogam. (*Id.* Ex. B-20 at 58.) These

⁷ The Nassau SAC states that Exhibit A lists the “specific drugs for which Nassau County seeks relief” and shows that MedImmune reported “false and inflated AWP’s for Synagis®.” (Nassau SAC ¶¶ 482, 485). Exhibit A, however, lists the allegedly “fraudulent AWP” and the alleged “market price” for a *different* MedImmune product: Cytogam. (Nassau SAC Ex. A at 29.) Exhibit B lists Synagis as the only MedImmune product for which Nassau County had expenditures. (*Id.* Ex. B. at 42.)

inconsistencies and inadequacies show the Plaintiffs abject failure to satisfy the specific pleading requirements set forth by this Court and Rule 9(b). They are further evidence that Plaintiffs lack a legitimate case against MedImmune.

CONCLUSION

Because Plaintiffs have failed to plead facts sufficient to state a claim against it, and because the generalized allegations in the Complaints fail to satisfy the heightened requirements of Rule 9(b), MedImmune respectfully requests that the Court dismiss all claims.

Dated: March 3, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 3, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2, by sending a copy of this document to Lexis/Nexis File & Serve for posting and notification to all parties.

/s/ James V. Hayes
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